Reference number(s)
5479-E

Initial Step Therapy with Quantity Limit; Post Step Therapy Prior Authorization with Quantity Limit
Vtama

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vtama	tapinarof

Indications

FDA-approved Indications

Plaque Psoriasis

Vtama cream is indicated for the topical treatment of plaque psoriasis in adults.

Atopic Dermatitis

Vtama cream is indicated for the topical treatment of atopic dermatitis in adults and pediatric patients 2 years of age and older.

Initial Step Therapy with Quantity Limit

Include Rx and OTC products unless otherwise stated.

If the patient has filled a prescription for at least a 30 day supply of a topical steroid within the past 180 days OR at least a one day supply of both a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid within the past 180 days (see Table 1) under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit.

If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the initial limit criteria will apply. If the patient is requesting more than the initial quantity limit the claim will reject with a message indicating that a PA is required.

Initial Limit Quantity

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Drug	1 Month Limit	3 Month Limit
Vtama (tapinarof) Cream 1%	60 grams / 25 days	180 grams / 75 days

TABLE 1: EXAMPLES OF TOPICAL CORTICOSTEROIDS FOR TREATMENT OF ATOPIC DERMATITIS [2,3,6]	
Medium Potency	betamethasone dipropionate lotion, spray 0.05%
Medium Potency	betamethasone valerate cream/lotion 0.1%/foam 0.12%
Medium Potency	clocortolone pivalate cream 0.1%
Medium Potency	desonide lotion, ointment 0.05%
Medium Potency	desoximetasone cream 0.05%
Medium Potency	fluocinolone acetonide cream/ointment/kit 0.025%
Medium Potency	flurandrenolide cream/ointment/lotion 0.05%
Medium Potency	fluticasone propionate cream/lotion 0.05%/ointment 0.005%
Medium Potency	hydrocortisone butyrate cream/lipocream/lotion/ointment/solution 0.1%
Medium Potency	hydrocortisone probutate cream 0.1%
Medium Potency	hydrocortisone valerate cream/ointment 0.2%
Medium Potency	mometasone furoate cream/lotion/solution 0.1%
Medium Potency	prednicarbate cream/ointment 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion/kit 0.1%
Medium Potency	triamcinolone acetonide cream/ointment/lotion 0.025%

Medium Potency	triamcinolone acetonide ointment 0.05%
High Potency	amcinonide cream/ointment/lotion 0.1%
High Potency	betamethasone dipropionate cream/ointment 0.05%
High Potency	betamethasone dipropionate augmented cream/lotion 0.05%
High Potency	betamethasone valerate ointment 0.1%
High Potency	desoximetasone cream/ointment/spray 0.25%/gel/ointment 0.05%
High Potency	diflorasone diacetate cream (emollient base) 0.05% diflorasone cream 0.05%
High Potency	halcinonide cream/ointment 0.1%
High Potency	fluocinonide cream/emulsified cream/ointment/gel/solution 0.05%
High Potency	mometasone furoate ointment 0.1%
High Potency	triamcinolone acetonide aerosol solution 0.147 mg/g
High Potency	triamcinolone acetonide cream/ointment 0.5%
Very High Potency	betamethasone dipropionate augmented ointment/gel 0.05%
Very High Potency	clobetasol propionate cream/ointment/foam/shampoo/gel/lotion/solution/spray 0.05%/cream 0.025%
Very High Potency	diflorasone diacetate ointment 0.05%
Very High Potency	flurandrenolide tape 4mcg/cm2
Very High Potency	halobetasol propionate cream/ointment/lotion/kit 0.05%
Very High Potency	fluocinonide cream 0.1%

Coverage Criteria

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the treatment of atopic dermatitis when ALL of the following criteria are met:

- The patient is 2 years of age or older
- The patient meets ONE of the following:
    - The requested drug will be used on sensitive skin areas (e.g. face, genitals, or skin folds) and the following criteria is met:
        - The patient experienced an inadequate treatment response, intolerance, OR has a contraindication to a topical calcineurin inhibitor
    - The patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires MORE than 60 grams per month

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the treatment of plaque psoriasis when ALL of the following criteria are met:

- The patient meets ONE of the following:
  - The patient as experienced an inadequate treatment response, intolerance OR the patient has a contraindication to a topical steroid
  - The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires MORE than 60 grams per month

Continuation of Therapy

Atopic Dermatitis

Authorization may be granted when the requested drug is being prescribed for the topical treatment of atopic dermatitis when ALL of the following criteria are met:

- The patient is 2 years of age or older
- The patient has achieved or maintained a positive clinical response as evidenced by improvement [(e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires MORE than 60 grams per month

Plaque Psoriasis

Authorization may be granted when the requested drug is being prescribed for the treatment of plaque psoriasis when ALL of the following criteria are met:

- The patient has achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.)
- If additional quantities are being requested, then the requested drug is being prescribed to treat a body surface area that requires MORE than 60 grams per month

Quantity Limits Apply

60 grams per 25 days or 180 grams per 75 days

For body surface areas requiring more than 60 grams per month: 120 grams per 25 days or 360 grams per 75 days

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Duration of Approval (DOA)

- 5479-E:
    - Atopic Dermatitis: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
    - Plaque Psoriasis: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

References

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3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 06/04/2024).
4. Menter A, Cordoro K, Davis D, et al. Guidelines of Care for the Management and Treatment of Psoriasis in Pediatric Patients. J Am Acad Dermatol. 2020;82(1):161-201.
5. Elmets C, Korman N, Farley Prater E, et al. Guidelines of Care for the Management and Treatment of Psoriasis with Topical Therapy and Alternative Medicine Modalities for Psoriasis Severity Measures. J Am Acad Dermatol. 2021; 84 (2):432-470.
6. Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71:116-32.
7. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol 2014; 70:338-51.
8. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023: 89(1): e1-e20.
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Document History

Written by: UM Development (DRS)

Reference number(s)
5479-E

Date Written: 05/2022

Revised: 06/2023 (added COT); (KMB) 06/2024 (no clinical changes); KMB/DMH 12/2024 (added atopic dermatitis indication)

Reviewed: Medical Affairs (CHART) 06/23/2022, 06/29/2023, 06/27/2024, 01/16/2025

External Review: 08/2022, 08/2023, 09/2024, 02/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the topical treatment of atopic dermatitis? [If Yes, then go to 2. If No, then go to 10.]	Yes	No
2	Is the patient 2 years of age or older? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is the request for continuation of therapy? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Has the patient achieved or maintained a positive clinical response as evidenced by improvement (e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
5	Will the requested drug be used on sensitive skin areas (e.g., face, genitals, or skin folds)? [If Yes, then go to 6. If No, then go to 7.]	Yes	No
6	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to a topical calcineurin inhibitor? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
7	Has the patient experienced an inadequate treatment response, intolerance or does the patient have a contraindication to a topical calcineurin inhibitor AND a medium or higher potency topical corticosteroid? [If Yes, then go to 8. If No, then no further questions.]	Yes	No
8	Is the requested drug being prescribed to treat a body surface area that requires MORE than 60 grams per month?	Yes	No

	[If Yes, then go to 9. If No, then no further questions.]		
9	Does the patient require MORE than the plan allowance of 120 grams per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 120 grams / 25 days OR 360 grams / 75 days.	Yes	No
10	Is the requested drug being prescribed for the treatment of plaque psoriasis? [If Yes, then go to 11. If No, then no further questions.]	Yes	No
11	Is the request for continuation of therapy? [If Yes, then go to 12. If No, then go to 15.]	Yes	No
12	Has the patient achieved or maintained a positive clinical response to the requested drug (e.g., clear, or almost clear outcome, patient satisfaction, etc.)? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Is the requested drug being prescribed to treat a body surface area that requires MORE than 60 grams per month? [If Yes, then go to 14. If No, then no further questions.]	Yes	No
14	Does the patient require MORE than the plan allowance of 120 grams per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 120 grams / 25 days OR 360 grams / 75 days.	Yes	No
15	Has the patient experienced an inadequate treatment response, intolerance or does the patient have a contraindication to a topical steroid? [If Yes, then go to 17. If No, then go to 16.]	Yes	No
16	Is the requested drug being used on sensitive skin areas (e.g., face, genitals, or skin folds)? [If Yes, then go to 17. If No, then no further questions.]	Yes	No
17	Is the requested drug being prescribed to treat a body surface area that requires MORE than 60 grams per month? [If Yes, then go to 18. If No, then no further questions.]	Yes	No

18	Does the patient require MORE than the plan allowance of 120 grams per month? [No further questions] RPH Note: If yes, then deny and enter a partial approval for 120 grams / 25 days OR 360 grams / 75 days.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 10	
2.	Go to 3	Deny	Your plan only covers this drug if you are 2 years of age or older. We reviewed the information we had. Your request has been denied. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Age]
3.	Go to 4	Go to 5	
4.	Go to 13	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
5.	Go to 6	Go to 7	
6.	Go to 8	Deny	Your plan only covers this drug if you have atopic dermatitis (eczema) on sensitive areas and have tried a topical calcineurin inhibitor, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a

			medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step therapy – sensitive areas]
7.	Go to 8	Deny	Your plan only covers this drug if you have tried a topical calcineurin inhibitor and a medium or higher potency topical corticosteroid, and they did not work well for you. We have denied your request because: A) You have not tried them, and B) You do not have a medical reason not to take them. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy - TCI and TCS]
8.	Go to 9	[PA Approved for 3 months. Approve 60 grams / 25 days OR 180 grams / 75 days]. Approve, 3 Months	
9.	Deny	[PA Approved for 3 months. Approve 120 grams / 25	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (120 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For

		days OR 360 grams / 75 days]. Approve, 3 Months	this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]
10.	Go to 11	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for psoriasis or atopic dermatitis. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]
11.	Go to 12	Go to 15	
12.	Go to 13	Deny	Your plan only covers this drug if it works well for you. We have denied your request because the drug did not work well for you. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation: Efficacy]
13.	Go to 14	[PA Approved for 12 months. Approve 60 grams / 25 days OR 180 grams / 75 days].	

		Approve, 12 Months	
14.	Deny	[PA Approved for 12 months. Approve 120 grams / 25 days OR 360 grams / 75 days]. Approve, 12 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (120 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]
15.	Go to 17	Go to 16	
16.	Go to 17	Deny	Your plan only covers this drug if you have tried a topical steroid, and it did not work well for you or the requested drug will be used on sensitive skin. We have denied your request because: A) You have not tried it, B) You do not have a medical reason not to take it, or C) You are not using it on sensitive skin. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy, Sensitive skin]
17.	Go to 18	[PA Approved for 4 months. Approve 60 grams / 25 days OR 180 grams / 75 days]. Approve, 4	

		Months	
18.	Deny	[PA Approved for 4 months. Approve 120 grams / 25 days OR 360 grams / 75 days]. Approve, 4 Months	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (120 grams per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial]